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| 09/741,881      | 12/22/2000  | Norman G. Anderson   | 2316-143            | 5632             |

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EXAMINER  
PADMANABHAN, KARTIC

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1641     |              |

DATE MAILED: 11/04/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/741,881

Applicant(s)

ANDERSON, NORMAN G.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the binding of particles in the sample to immobilized binding agent. While the term "capable" when referring to binding of the particle may not render the claim indefinite (acquiescing to applicant's argument in this regard), it is unclear if the claim actually requires binding of the immobilized agent and particle in the sample. If the claim does not, then the claimed method seems inoperative, as how would one be able to detect particles bound to the immobilized binding agent without the positive recitation of such binding? As such, the claim is missing essential method steps.
4. Claim 1 is rejected as vague and indefinite for the recitation of "containing a first slanted solid phase at a location above the first slanted solid phase" because how can the same slanted phase be above itself? It appears that applicant is attempting to claim that the sample is placed into the sedimentation container above the first slanted solid phase, in which case, applicant should place the modifying clause next to the phrase it is modifying.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nath (WO 86/07463). The reference teaches methods for the detection of antibodies, wherein a slanting solid phase in a microtiter well is coated with antibodies to a protein. The test sample is added to the well and incubated such that binding may occur between sample and the solid phase. After unbound sample is removed, particle coated with antigens specific to the antibodies are added, and captured antibody-antigen complexes are separated (page 13). The microtiter well may be a 'V' shaped well, and the test sample may be a body fluid, such as blood plasma or serum. The particle of the reference may be red blood cells (page 14). However, the reference does not teach the use of an additional slanted solid phase to concentrate the particles.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of

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the invention to concentrate the particles of interest over another solid phase, as this would allow for greater binding efficiency. One of skill in the art would have known that the greater the concentration of target analyte in a given area, the greater the binding efficiency to any binding agents they contact. Further, it would have been obvious to use centrifugation with the method of the reference to achieve sedimentation and binding more rapidly, just as it would have been obvious to use a density gradient during sedimentation, which would obviate the need for removing unbound sample prior to the addition of antibody-specific antigen.

8. Claims 1-10 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US Pat. 6,254,834). The reference teaches methods for the detection and characterization of microorganisms using sedimentation rate and binding density. The method comprises ultracentrifugation of a sample containing the microorganisms in an ultracentrifuge tube. This ultracentrifugation step may include the formation of density gradients and/or the staining of the microorganisms using fluorescent dyes (Col. 5, lines 1-19). The centrifuge tube of the reference has a slanted bottom surface, as seen in Figures 2A-2C. The method of the reference may also include the step of exposing the microorganisms to reagents, including detergents, surfactants, and enzymes, contained and immobilized in distinct zones in a density gradient to dissolve contaminating particles (col. 6, lines 42-50). In addition, fluorescent particles of known density may be included in the sample to assist in identifying particles by density (Col. 13, line 65 – Col. 14, line 10). However, the reference only teaches restricting the movement of reagents within the second slanted solid phase and does not teach reagent immobilization.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize binding reagents on the second solid phase with the method of Anderson et al. because such an arrangement increases binding efficiency by ensuring contact

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between the target and the immobilized reagents. Further, one would have had a reasonable expectation of success in making this modification, as both restricting reagent movement to specific zones and reagent immobilization both have the same effect of restricting the movement of reagents to specific areas of the solid phase.

***Response to Arguments***

9. Applicant's arguments with respect to claims 1-10 and 28-30 have been considered but are moot in view of the new ground(s) of rejection. However, it is noted that the Anderson, which was previously withdrawn as a rejection under 35 USC 102 (e), has, upon reconsideration, been applied under 35 USC 103.

***Conclusion***

Claims 1-10 and 28-30 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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CHRISTOPHER L. CHIN  
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